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UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF CALIFORNIA

LATONIA CRAWFORD, Plaintiff, vs. ZIMMER BIOMET HOLDINGS, INC., f/k/a ZIMMER HOLDINGS, INC.; ZIMMER BIOMET, INC., f/k/a ZIMMER, INC., and DOES 1 to 20, Defendants.	Case No.: 1:21-CV-00988-AWI-JLT **NOTICE OF MOTION AND MOTION TO FILE AMENDED COMPLAINT** Date: June 15, 2022 Time: 9:30 AM Dept: 7, 6th floor United States Magistrate Judge Sheila K. Oberto

NOTICE OF MOTION AND MOTION FOR LEAVE TO FILE AMENDED COMPLAINT

PLEASE TAKE NOTICE that on June 15, 2022, at 9:30 a.m., or as soon thereafter as the matter can be heard, in the courtroom of the United States Magistrate Judge Sheila K. Oberto, located at 500 Tulare Street, Fresno, CA 93721, Plaintiff, Latonia Crawford ("Plaintiff") will, and hereby does, move for an order granting Plaintiff leave to file her Amended Complaint and ordering that the Amended Complaint submitted with this motion be deemed filed.

The motion will be based on this Notice of Motion and Motion, the Memorandum of Points and Authorities, Plaintiff's Amended Complaint, and the [Proposed] Order filed herewith, on all of the files and records of this action, and on any additional material that may be elicited at the hearing of this motion.

MEMORANDUM OF POINTS AND AUTHORITIES

I. INTRODUCTION

Through this motion, Plaintiff seeks leave to file its Amended Complaint pursuant to Federal Rule of Civil Procedure 15(a) and this Court's September 20, 2021 Case Management Order. Plaintiff's Amended Complaint, attached hereto as Exhibit A, adds new Causes of Action and facts to support Plaintiff's claim with more specificity as to the inherently dangerous nature of Defendant's Medical Equipment, alleging a design defect instead of a claim of manufacturing defect, and additional factual allegations relating to Plaintiff's previously asserted claims and Doe defendants. Plaintiff's Amended Complaint is timely, does not cause any prejudice to Defendants and should be permitted.

II. STATEMENT OF FACTS

Plaintiff filed this lawsuit on May 11, 2021. Defendants Zimmer Biomet Holdings, Inc., F/K/A Zimmer Holdings, Inc.; Zimmer Biomet, Inc., F/K/A Zimmer, Inc.; Zimmer Biomet U.S., INC., Corporation ("Defendants") answered on June 23, 2021.

In the Case Management Statement, filed September 20, 2021, amended by this Court's Order of April 15, 2022, the parties agreed, and the Court Ordered, that all Non-Dispositive Motions shall be heard by November 21, 2022.

Since filing the complaint, Plaintiff has discovered additional information necessitating the filing of this Amended Complaint. Plaintiff's counsel contacted Defendants' counsel to seek Defendants' written consent to the amendment pursuant to Federal Rule of Civil Procedure 15. However, Defendants has not consented to the filing of this Amended Complaint as of the time of this filing. Accordingly, Plaintiff seeks an order permitting Plaintiff to file the proposed Amended Complaint.

III. ARGUMENT

A. Leave Should Be Granted To Amend the Complaint.

1. Leave Is Freely Granted.

Federal Rule of Civil Procedure 15(a) provides that leave to amend a pleading "shall be freely given when justice so requires." The United States Supreme Court, the Ninth Circuit, and this Court have repeatedly reaffirmed that leave to amend is to be granted with "extreme liberality." *DCD Programs, Ltd. v. Leighton*, 833 F.2d 183, 186 (9th Cir. 1987) (citation omitted); *see, e.g., Foman v.Davis*, 371 U.S. 178, 182, 83 S. Ct. 227, 230 (1962) (leave to amend should be freely given); *Eminence Capital, LLC v. Aspeon, Inc.*, 316 F.3d 1048, 1052 (9th Cir. 2003) ("Absent prejudice, or a strong showing of any of the remaining *Foman* factors, there exists a *presumption* under Rule 15(a) in favor of granting leave to amend.") (emphasis in original); *United States v. Webb*, 655 F.2d 977, 979 (9th Cir. 1981) (courts should be guided by policy favoring decisions on the merits "rather than on the pleadings or technicalities"); *Cooper Development Co. v. Employers Insurance of Wausau*, 765 F. Supp. 1429, 1432 (N.D. Cal. 1991) (courts have been "quite liberal" in granting leave to amend); *Building Service Employees Pension Trust v. Horsemen's Quarter Horse Racing Association*, 98 F.R.D. 458, 459 (N.D. Cal. 1983) (same); *see also* Moore, *3-15 Moore's Federal Practice - Civil* § 15.14 ("A liberal, pro-amendment ethos dominates the intent and judicial construction of Rule 15(a)."). The primary factors relied upon by the Supreme Court and the Ninth Circuit in denying a motion for leave to amend are "bad faith, undue delay, prejudice to the opposing party, and futility of amendment." *DCD Programs*, 833 F.2d at 186. None of these factors are present here.

B. Amendment Should Be Permitted.

Plaintiff's Amended Complaint is timely and should be allowed. In its Case Management Order, this Court did not set deadlines to amend to add new claims and/or parties. There is a November 21, 2022 deadline for non-dispositive Motions, and this

Motion is being filed prior to that deadline. Furthermore, Plaintiff falls well within the liberal standard for freely allowing the amendment of pleadings. See *Foman v. Davis*, 371 U.S. 178, 182 (1962) ("In the absence of . . . undue delay, bad faith or dilatory motive on the part of the movant . . . undue prejudice to the opposing party by virtue of allowance of the amendment . . . the leave sought should, as the rules require, be 'freely given.'")

There is no prejudice to Defendants here. Plaintiff's Amended Complaint does not change the nature of the lawsuit, nor is Defendants precluded from seeking discovery in relation to the Amended Complaint. The deadline to complete discovery in this case is not until July 6, 2022, and Plaintiff has offered to extend those deadlines to complete any necessary discovery. Indeed, Defendants just received Plaintiff's responses to initial discovery. It was while preparing those responses that Plaintiff's counsel discovered the additional information and need to Amend. Accordingly, Defendants will not be prejudiced by an order granting leave to file Plaintiff's Amended Complaint. Moreover, Plaintiff offers its Amended Complaint in good faith and without undue delay. Since filing its original complaint, Plaintiff has discovered new information regarding Defendants' products and marketing. This information supports Plaintiff's new claims and theories as well as Plaintiff's assertion of additional details in support of its previously asserted claims. *See Coilcraft, Inc. v. Inductor Warehouse*, 2000 U.S. Dist. LEXIS 6097, *8-9 (no bad faith where plaintiff made "reasonable inquiry" into facts supporting new claim, introduced relevant evidence, and "has never mischaracterized the nature of the lawsuit").

In sum, Plaintiff's Amended Complaint was filed timely and in good faith, contains claims similar to those originally asserted and does not prejudice Defendants. Consequently, none of the factors on which courts base denial of motions for leave to amend are present here. Thus Plaintiff's motion for leave should be granted.

IV. CONCLUSION

For the reasons discussed above, plaintiff respectfully seeks leave of this Court to file the proposed Amended Complaint.

Respectfully submitted

Date: May 4, 2022

JOSEPH FARZAM LAW FIRM

BY: Michael P. Green, Esq.
Counsel for Plaintiff,
LATONIA CRAWFORD

EXHIBIT A

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UNITED STATES DISTRICT COURT

EASTERN DISTRICT OF CALIFORNIA

LATONIA CRAWFORD, Plaintiff, v. ZIMMER BIOMET HOLDINGS, INC., f/k/a ZIMMER HOLDINGS, INC.; ZIMMER BIOMET, INC., f/k/a ZIMMER, INC.; ZIMMER BIOMET U.S., INC., and DOES 1 to 20, Defendants.	Case No.: 1:21-CV-00988-AWI-BAK (SKO) **FIRST AMENDED COMPLAINT FOR DAMAGES**

Plaintiff LATONIA CRAWFORD states the following First Amended complaint against the Defendants:

SUMMARY

1. This is a medical device products liability case based upon Defendants' manufacture, distribution, marketing, and labeling of hip components that proximately caused Plaintiff to suffer economic and noneconomic damages.

JURISDICTION AND VENUE

2. Plaintiff is an adult woman living in Kern County, as she was at all times relevant.

3. The injury that caused Plaintiff to suffer economic and noneconomic damages occurred in Bakersfield, California.

4. Zimmer Biomet Holdings, Inc., formerly known as Zimmer Holdings, Inc., is a corporation organized under the laws of the state of Delaware, with its principal place of business in the state of Indiana. At all times relevant to this action, Zimmer Biomet Holdings, Inc. was the publicly traded holding company with wholly owned subsidiaries that it controlled which manufactured, distributed, marketed, and labeled the hip components that caused Plaintiff to suffer economic and noneconomic damages. These components were placed in interstate commerce and throughout the State of California, generating substantial revenue as a result.

5. Zimmer Biomet, Inc. formerly known as Zimmer, Inc., is a corporation organized under the laws of the state of Delaware, with its principal place of business in the state of Indiana. At all times relevant to this action, Zimmer Biomet, Inc. was a wholly owned subsidiary of Zimmer Biomet Holdings, Inc. On April 24, 2014, Zimmer Holdings, Inc. entered into an agreement to merge with LVB Acquisition, Inc., the parent company of Biomet, Inc. After the merger, Zimmer Holdings, Inc. was renamed Zimmer Biomet Holdings, Inc. and Zimmer, Inc. was renamed Zimmer Biomet, Inc. At all times relevant to this action, Zimmer Biomet, Inc. manufactured, distributed, marketed, and labeled the hip components that caused Plaintiff to suffer economic and noneconomic damages. These components were placed in interstate commerce and throughout the State of California, generating substantial revenue as a result.

6. Zimmer Biomet U.S., Inc., formerly known as Zimmer U.S., Inc., is a corporation organized under the laws of the state of Delaware, with its principal place of business in the state of Indiana. At all times relevant to this action, Zimmer Biomet U.S., Inc. was a wholly owned

subsidiary of Zimmer Biomet, Inc. At all times relevant to this action, Zimmer Biomet U.S. manufactured, distributed, marketed, and labeled the hip components that caused Plaintiff to suffer economic and noneconomic damages. These components were placed in interstate commerce and throughout the State of California, generating substantial revenue as a result.

7. Plaintiff is presently ignorant of the true identities of the Defendants sued herein as DOES 1- 20 and therefore sues them by such fictitious names. DOES 1 - 20 are somehow liable to Plaintiff for the transactions, occurrences, and damages alleged herein.

8. Zimmer Biomet was founded in 1927. Globally, it is the third largest orthopedic device firm in the United States.

9. This is a lawsuit over defective hip implant components designed, marketed, manufactured, promoted and sold by Defendants Zimmer Biomet Holdings, Inc., F/K/A Zimmer Holdings, Inc.; Zimmer Biomet, Inc., F/K/A Zimmer, Inc.; Zimmer Biomet U.S., Inc., of which U.S. District Court for the Eastern District of California has original jurisdiction under 28 U.S.C. section 1332 because it is between citizens of different states (as described above) and the amount in controversy exceeds the sum or value of $75,000, exclusive of costs and interest.

FACTS

10. Plaintiff incorporates all foregoing paragraphs herein as though fully set forth.

11. On or about November 11, 2014, Plaintiff underwent a left hip arthroplasty. The implants included but are not limited to:

- Biomet Modular Taberloc Femoral, porous coated, size 7.5, type I taper, Titanium Alloy Ti-6AL-4V, Ref./Catalog #103202, Lot #521400;
- Biomet Modular Femoral Head, CoCrMo Alloy, 36mm, type 1 taper, -6, Ref./Catalog #11-363660, Lot #583130;

- Biomet Low Profile Self-Tapping Bone Screw, 6.5mm x 30mm, Ref./Catalog #103533, Lot #374270
- Biomet E1 RingLoc Acetabular Liner, 36mm, Size 23, +3 Maxrom, Antioxidant Infused UHMWPE, Ref./Catalog #EP-108223, Lot #775640
- Biomet Universal Ringloc 2-Hole Shell, 52 mm with artificial dome hole, Liner Size 23, porous coated, Titanium Alloy Ti-6AL-4V/CP Titanium, Ref./Catalog #14-103652, Lot #961440

12. Between November 11, 2014 and December 26, 2015, the components placed in Plaintiff to replace her hip dislocated several times and the hip had to be reset into place. Ultimately, it was decided to have another surgery to better secure the hip.

13. On or about December 26, 2014, Plaintiff had open reduction and revision of the acetabular component in response to dislocation of the left hip (femoral) prosthesis. The implants used included but are not limited to:

- Biomet Acetabular Lock Ring, Size 23, CP Titanium, Ref./Catalog #105423, Lot #924430
- Biomet E1 Ringloc Acetabular Liner, 36mm, Size 23, +3 Maxrom, Antioxidant Infused, Ref./Catalog #EP-108323, Lot #867960
- Biomet Modular Femoral Head, CoCrMo Alloy, 36mm, type 1 taper, -6, Ref./Catalog #11-363660, Lot #332920

14. On or about December 26, 2014, upon opening Plaintiff's hip and examining the hardware implanted, it was discovered that:

- The acetabular lock ring had displaced;
- The Acetbular liner was insufficiently low and had to be rebuilt;

- The femoral head was scuffed from the prior dislocations and had to be replaced.

15. In 2015, Plaintiff's hip dislocated and the acetabulum was inspected. It was discovered that the posterior wall of the acetabular liner had fractured into several pieces. As a result, on or about February 24, 2015, Plaintiff underwent an open reduction and revision of the acetabular liner. The implants used included but are not limited to:

- Biomet Acetabular Lock Ring, Size 23, CP Titanium, Ref./Catalog #105423
- Biomet Freedom Constrained Liner, 36mm, Size 23, Standard Face, +5, ArCom polyethylene liner, Titanium Alloy Ti-6AL-4V constraint ring, Ultrum Ref./Catalog #11-107022
- Biomet Freedom Modular Head, 36mm, type 1 taper, -6, CoCrMo Alloy, Ref./Catalog #11-107016

16. On or about February 24, 2015, during the course of revision surgery, it was discovered that:

- The posterior wall of the total hip liner had fractured off in several pieces of the poly were within the acetabulum;
- The associated ring lock mechanism had failed and had to be replaced.

17. On or about November 23, 2019, Plaintiff had revision of her left hip arthroplasty because the constrained Freedom acetabular cup, liner, and head had broken, resulting in pseudotumor formation and metallosis.

18. During the course of surgery on November 23, 2019, it was discovered that:

- The Left hip had a broken metal head;
- There was a broken acetabular cup;

- Plaintiff was suffering from Metallosis, which is a type of metal poisoning that can occur as a side effect of joint replacement devices with metal components, such as metal-on-metal hip replacements or other metal implants. When the metal parts rub against each other, they release microscopic metal particles into the blood and surrounding tissues.
- The Metallosis had caused pseudotumor formation about the hip and pelvis
- The Freedom constrained liner was broken at the base of the cup due to mechanical impingement with flexion.
- The ring of the liner was broken as well

19. Subsequent to this procedure, and in discussions with her surgeon, Plaintiff discovered that the equipment supplied by Defendants had failed, rusting in multiple hip dislocations and necessity of revision surgery. As a result of the multiple failures, and resultant metal on metal mechanical operation of her hip, Plaintiff discovered that she had been caused to be afflicted with Metallosis, a chronic condition which causes lifelong symptoms and disabilities. Prior to this, Plaintiff had not been informed, nor was she aware, of the defective equipment and terrible malady that it caused.

20. The medical professionals who used Biomet implants on Plaintiff did so in a manner consistent with that foreseen and promoted by Defendants.

21. Plaintiff did not act in any manner that contributing to the harm caused by Defendants' products.

22. The Biomet implants used on Plaintiff had dissimilar metals - including a titanium and cobalt-chrome alloy.

23. The acetabular liner that was found to have fractured in 2015 was made of a Vitamin E-infused highly cross-linked polyethylene. The Freedom Constrained Liner that failed,

contributing to Plaintiff's pseudotumor formation and metallosis, was made of a traditional ArCom polyethylene.

GENERAL FACTUAL ALLEGATIONS

24. Defendants were the designers, manufacturers, and suppliers of the Hip System and related components in the business of putting medical devices on the market.

25. Defendants warranted the Hip System and placed the device into the United States stream of commerce.

26. Before they set out to design the Hip System, Defendants knew of the danger to human beings if cobalt-chromium metal debris from its products were released into the body through corrosion, micromotion, and/or fretting.

27. Before placing the Hip System on the market, Defendants were required to mitigate risks of the product, including any element of the design that created toxic levels of corrosion and debris that could result in pain, swelling, pseudotumor formation, osteolysis, instability, dislocation, metallosis, trunnionosis, adverse tissue reaction and/or the need for early surgical revision in patients-consumers.

28. The Hip System taper is designed with threading on the taper. This threading can be described as shallow grooves on the portion of the taper that articulates with the head. This threading on the taper is used to comply with the requirements of the manufacturer of ceramic head option, CeramTec.

29. The significance of the Defendants' Hip System taper threading is (1) it protects ceramic heads and (2) provides an interface at the junction with a metal head which is much more likely to produce wear and debris under fretting conditions. The

threads were not designed to enhance the performance of metal heads.

30. The decision to allow the use of metals and CoCr heads (rather than ceramic heads) in the Defendants' Hip System created an unreasonable risk and made it defective.

31. The concept that that corrosion might occur at the head-neck taper junction of a total hip prosthesis was first described in the early 1980s. When Defendants were designing the Hip System this concept had to be a consideration.

32. In designing the Hip System, Defendants knew that the use of dissimilar metal alloys as well as taper size and geometry, trunnion surface finish, and flexural rigidity contribute to causing fretting and corrosion at the femoral head- neck/stem taper interface.

33. Mechanically assisted crevice corrosion ("MACC") has been identified as a cause for symptomatic implant failure in metal-on-polyethylene hip devices. MACC produces cobalt and chromium ions, fretting byproducts and corrosive debris that can lead to adverse local tissue reaction.

34. Adverse local tissue reaction, also referred to as aseptic lymphocyte dominated vasculitis-associated lesions ("ALVAL"), represents a distinctive periprosthetic inflammatory reaction accompanied by extensive necrosis in the soft tissue-envelope of the hip. Early detection of adverse local tissue reaction is important because as time from onset of MACC to revision surgery increases, tissue damage may worsen.

FAILURE TO WARN PHYSICIANS OF THE DANGERS ASSOCIATED WITH THE DEFENDANTS'HIP SYSTEM

35. Zimmer marketed its hip implants, including the ones utilized for Plaintiff, to orthopedic surgeons and hospitals rather than end-user patients.

36. Defendants had the ability to inform surgeons or hospitals of developing problems or defects in its devices through e-mail, letter, recalls, warnings in product inserts and/or through its product representative(s), who works directly with the surgeon.

37. The mechanical environment of the junction place the Defendants' Hip System at increased risk for failure from pain, swelling, pseudotumor formation, metallosis, adverse local tissue reaction, synovitis, osteolysis, and/or dislocation, resulting from excessive wear debris, fretting corrosion and recurrent repassivation.

38. The fretting process (mechanical micromotion) is strongly influenced by distribution of pressure and force at the junctions, rendering these junctions vulnerable to accelerated generation of metal wear debris and corrosion.

39. Each interface introduces a contributing source for metal wear particular and debris generation. These junctions exponentially compound and accelerate the wear debris generation process.

40. Corrosion is time-sensitive and accelerated with mechanical stresses. This phenomenon was known to Defendants, or should have been known by Defendants, at all times relevant to the design, manufacture, marketing and sale of the Hip System.

41. At the time of design, manufacture, testing and marketing, Defendants knew or should have known, combinations of metal alloys at a junction, such as the metal CoCr heads and cobalt-chromium and/or titanium neck/stem junctions of the Hip System, generate excessive fretting, corrosion and metal wear debris.

42. Defendants did not inform or warn and is still not informing or warning physicians or consumers either through its sales representatives, correspondence, advertising or package inserts that:

a. Selection of a metal CoCr head rather than a ceramic head to pair with the cobalt-chromium and/or titanium neck/stem significantly increases the risk of toxic amounts of corrosion and metal debris which might cause pain; swelling; metallosis; trunnionosis; tissue necrosis; adverse local tissue reaction; osteolysis; dislocation; and/or the need for early revision;

b. Upon information and belief, Defendants' pre-market corrosion testing, if any, was inadequate as it pertains to the Defendants' Hip System; and/or,

c. Upon information and belief, Defendants' Spectrum Accelerated Corrosion Fatigue ("SACF") Testing, if any, was inadequate as it pertains to the Defendants' Hip System.

37. Defendants never performed any clinical trials and/or studies prior to marketing the Hip System.

38. Defendants did not fully and/or adequately test the configuration utilizing CoCr femoral heads and cobalt-chromium and/or titanium neck/stem junctions that were implanted into Plaintiff.

39. Defendants continue to market the CoCr heads for use with the cobaltchromium and/or titanium neck/stems in the Hip System.

40. Reassurances of device safety were made through direct promotional contact by Defendants' sales representatives and distributors, through word-of-mouth from Defendants'' physician/technical consultants, and/or through industry targeted promotional materials.

41. Despite these reassurances, the defective design and manufacture of the Defendants' Hip System, with a CoCr femoral head, generates excessive fretting and corrosion occurring at the head-neck/stem taper junctions. The fretting and corrosion generates toxic metal debris, metal ions and other chemical byproducts which are released into the surrounding tissues. These metal debris, metal ions and byproducts destroy the

surrounding tissue and bone, often causing pseudotumors and other metal related conditions. The release of metal debris and metal ions also causes systemic exposure to the toxic metallic elements often reflected in elevated blood serum and/or urine testing levels.

42. Defendants were aware of the problems at the time that they designed, manufactured, marketed, distributed, and/or sold the Hip System.

43. Nonetheless, Defendants employed the design in the Defendants' Hip System in reckless disregard for the safety of patients, including Plaintiff. Indeed, Defendants elected to "maximize our return on our investment of time and resources. In other words, we want to get the "biggest bang for our development buck". This would mean that we should prioritize our work and develop the products that will make the most money for [Defendants] first."

44. Moreover, despite direct knowledge of significant adverse events reported by patients and physicians, as well as awareness of failures that have been reported in the literature and published in national registries, Defendants have continued to market the Hip System as being safe and effective with the CoCr femoral head. This, despite that by July of 2019, over 3,700 lawsuits had been filed against Defendants alleging failures and damages similar to Plaintiff's regarding the Hip System.

45. From the time that Defendants first began selling the Hip System in the United States through today, its product labeling and product information failed to contain adequate information, instructions, and warnings concerning implantation of the product, specifically with the use of a CoCr femoral head, and its increased risks of fretting and corrosion.

46. The problems with the Defendants' Hip System are similar in nature to the issues that gave rise to Stryker Orthopedics' recent recall of the LFIT® Anatomic CoCr V40™ Femoral Heads on August 29, 2016. Both the LFIT® Anatomic CoCr V40™ Femoral Heads and the Versys Femoral Heads are made of cobalt-chromium and both are

mated with metal alloy stems. Stryker's Urgent Medical Device Recall Notification states that the company initiated the worldwide recall after receiving higher than expected complaints of "taper lock failure" which could result in numerous potential hazards including but not limited to excessive metal debris, excessive wear debris, disassociation of the femoral head from the hip stem and fractured hip stem trunnion leading to adverse local tissue reaction, implant loosening, loss of mobility, and pain requiring revision

THE FDA'S 510(k) CLEARANCE PROCESS

47. The 510(k) clearance process refers to Section 510(k) of the Medical Device Amendments of 1976 (hereafter "MDA") of the Federal Food, Drug and Cosmetic Act. Under this process, device manufacturers are only required to notify the FDA at least 90 days before they market a device claimed to be "substantially equivalent" to a device the FDA approved for sale prior to 1976, when the MDA was enacted.

48. No clinical testing is required under this process.

49. Subsequent amendments to the MDA allowed for 510(k) clearance for products deemed "substantially equivalent" to post-MDA, 510(k) cleared devices.

50. Through this domino effect, devices deemed "substantially equivalent" to devices previously deemed "substantially equivalent" to devices approved for sale by the FDA prior to 1976 could be sold to patients in a matter of 90 days without any clinical testing.

51. Clearance for sale under the 510(k) process does not equate to FDA approval of the cleared device.

52. In 2012, at the request of the FDA, the National Institute of Health (hereafter "NIH") conducted a thorough review of the 510(k) process, coming to the following major conclusions:

> The 510(k) clearance process is not intended to evaluate the safety and effectiveness of medical devices with some exceptions. The 510(k) process cannot be transformed into a pre-market evaluation of safety and effectiveness so long as the standard for clearance is substantial equivalence to any previously cleared device.

53. The NIH explained, "The assessment of substantial equivalence does not require an independent demonstration that the new device provides a 'reasonable assurance of safety and effectiveness.'" Further, the NIH even pointed out that the classification of predicate devices approved for sale prior to the 1976 MDA "did not include any evaluation of the safety and effectiveness of individual medical devices . . . Thus is common for devices to be cleared through the 510(k) program by being found substantially equivalent to devices that were never individually evaluated for safety and effectiveness, either through the original device classification program or through the 510(k) process."

54. Defendants cleared the Hip System, and its related components, under a process used by the United States Food and Drug Administration known as the 510(k) Premarket Notification. Under Section 510(k) of the Federal Food, Drug and Cosmetic Act, a medical device does not have to go through the rigors of a clinical study to gain approval by the FDA. Instead, the device is supposed to demonstrate substantial equivalence to a predicate medical device.

55. The first components of Defendants' Hip System were cleared for sale in the United States according to Section 510(k) in October 2003.

FIRST CAUSE OF ACTION
Strict Products Liability – Unreasonably Dangerous Design

56. Plaintiff incorporates by reference paragraphs 1 through 55 of this Complaint, as if fully set forth herein and further allege as follows:

57. The Defendants had a duty to design and manufacture, and to place into the stream of commerce, distribute, market, promote and sell, the Hip System so that it was neither defective nor unreasonably dangerous when put to the use for which it was designed, manufactured, distributed, marketed and sold.

58. On and prior to November 11, 2014, Defendants were engaged in the business of designing, manufacturing, marketing, distributing and selling orthopedic hip implants and did design, manufacture, distribute, market and sell the Hip System that was implanted into the left hip of Plaintiff, as well as the subsequent replacements made after the original parts failed.

59. Defendants were engaged in selling, distributing, supplying and/or promoting the Hip System to Plaintiff and her implanting physician.

60. Defendants expected the Hip System they were selling, distributing, supplying, manufacturing and/or promoting to reach, and it did in fact reach, implanting physicians and consumers in the State of California, including Plaintiff and her implanting physician, without substantial change in the condition.

61. Plaintiff is in the class of persons that Defendants should reasonably foresee as being subject to the harm caused by the defectively designed Hip System, insofar as Plaintiff was the type of person for whom the hip implants were intended to be used.

62. At the time the Hip System left the Defendants' possession and the time the Hip System entered the stream of commerce in the State of North Carolina, it was in an unreasonably dangerous or defective condition. These defects include, but are not limited to, the following:

a. the Hip System was not reasonably safe as intended to be used;

b. the Hip System had an inadequate design for the purpose of hip replacement;

c. the Hip System contained unreasonably dangerous design defects, including an inherently unstable and defective design paired with a Cobalt-Chromium femoral head, which resulted in an unreasonably high metal wear debris, corrosion, fretting and probability of early failure;

d. the Hip Systems' unstable and defective design resulted in a hip prosthesis which had risks which exceeded the benefits of the medical device;

e. the Hip System was not appropriately or adequately tested before its distribution; and

f. the Hip System had an unreasonably high propensity for corrosion, fretting and fatigue under normal and expected use of the Hip System.

63. At the time of the Defendants' initial design and manufacture, and of all Defendants' marketing and sale of the Hip System, a feasible, alternative safer design for the Hip System was known and available, including, but not limited to, a design that utilized a ceramic femoral head and monoblock design. A ceramic head would reduce and/or eliminate metal debris and particles.

64. At the time of and subsequent to the Defendants' initial design and manufacture, marketing and sale of the Hip System, including prior to the time of Plaintiff's initial hip implant surgery, Defendants had the ability to eliminate the unsafe character of the Hip System without impairing its usefulness.

65. Had the Defendants properly and adequately tested the Hip System, they would have discovered that the components, paired with a cobaltchromium femoral head, generated excessive metal wear caused by the surface contact of the metal articulating components resulting in pain, swelling, metallosis, tissue necrosis, bone necrosis, and a host of other maladies.

66. The Hip System devices, manufactured, supplied, distributed, marketed, promoted and sold by Defendants, were, therefore, defective in design or formulation in that, when they left the hands of Defendants, the foreseeable risk of harm from the product exceeded or outweighed the benefit or utility the consumer would expect, and/or it failed to comply with federal requirements for these medical devices.

67. At all times relevant hereto, Plaintiff and Plaintiff's healthcare providers used the Defendants' Hip System for its intended or reasonably foreseeable purpose, and pursuant to instruction, guidance, education and training provided by Defendants or

agents of Defendants.

68. At all times relevant hereto, the Hip System was dangerous, unsafe and defective in design including but not limited to its tendency to: (a) create dangerous and harmful metal debris in the patient's body; (b) cause pain; (c) inhibit mobility; and (d) require revision surgery with predictable cascading complications.

69. Defendants knew or should have known of the unreasonably dangerous and serious risks associated with the design of the Hip System.

70. Such risks were scientifically knowable to Defendants.

71. Defendants knew or should have known of the dangers.

72. Defendants either performed inadequate evaluation and testing; kept themselves willfully blind to the dangers; hid the dangers from physicians and patients, or some combination of the three.

73. As a direct, legal, and proximate result of Defendants' dangerous design, Plaintiff sustained injuries as set forth above.

74. Defendants' dangerous design and failure to adequately test contributed to cause the injuries suffered by Plaintiff.

75. As a direct and proximate result of Defendants' wrongful conduct, including the defective and dangerous design and inadequate warnings of the Hip System, Plaintiff has sustained and will continue to sustain severe and debilitating injuries, economic loss, and other damages including, but not limited to, cost of medical care, rehabilitation, lost income, permanent instability and loss of balance, immobility, and pain and suffering, for which she is entitled to compensatory and equitable damages and declaratory relief in an amount to be proven at trial.

SECOND CAUSE OF ACTION

Strict Products Liability – Failure to Warn

76. Plaintiff incorporates by reference paragraphs 1 through 75 of this Complaint, as if fully set forth herein and further allege as follows:

77. Defendants researched, developed, designed, tested, manufactured, inspected, labeled, distributed, marketed, promoted, sold, and otherwise released into the

stream of commerce the Hip System, in the course of same, directly advertised or marketed the product to the FDA, health care professionals, and consumers, including the Plaintiff, or persons responsible for consumers, and therefore had a duty to warn of the risks associated with the use of the Hip System.

78. Defendants distributed and sold the Hip System devices in their original form of manufacture, which included the defects described herein.

79. The Defendants' Hip System was defective and unreasonably dangerous when it left the possession of Defendants in that it contained an absence of warnings or limitations on when such device should be selected over safer alternatives.

80. The Defendants' Hip System was defective and unreasonably dangerous when it left the possession of Defendants in that it contained an absence of warnings alerting the medical community and patients as to the dangerous risks associated with the Hip System when used for its intended and reasonably foreseeable purpose.

81. The risks associated with the Defendants' Hip System when used for its intended and reasonably foreseeable purpose, include but are not limited to: (a) the creation of dangerous and harmful metal debris in the patient's body; (b) pain; (c) mobility inhibition; and (d) likelihood of revision surgery with predictable cascading complications.

82. The Defendants' Hip System was expected to and did reach Plaintiff and her implanting physician, in the State of California without substantial change or adjustment in its condition as manufactured and sold by Defendants.

83. The Defendants' Hip System devices designed, developed, tested, manufactured, distributed, promoted, marketed and/or sold or otherwise placed into the stream of commerce by Defendants were in a dangerous and defective condition and posed a threat to any user or consumer of the Defendants' Hip System devices.

84. At all times relevant hereto, Plaintiff was a person the Defendants should have considered to be subject to the harm caused by the defective nature of the Defendants' Hip System devices.

85. Defendants' Hip System was implanted in Plaintiff and used in the manner for which it was intended.

86. This use has resulted in severe physical, financial, emotional and other injuries to Plaintiff.

87. Defendants failed to adequately warn health care professionals and the public, including Plaintiff and his prescribing physician, of the true risks of their Hip System, including that the Defendants' Hip System was susceptible to micromotion, fretting and corrosion at the junction, generating significant and toxic amounts of metal wear debris and corrosive byproducts in patients, causing severe pain and injury, and requiring further treatment, including revision surgeries and/or hip replacements.

88. Defendants failed to timely and reasonably warn of material facts regarding the safety and efficacy of the Defendants' Hip System. Had they done so, proper warnings would have been heeded and no health care professional, including Plaintiff's physician would have used the Defendants' Hip System, or no consumer, including Plaintiff, would have purchased and/or used the Defendants' Hip System.

89. Defendants failed to timely and reasonably provide adequate instructions and training concerning safe and effective use of the Defendants' Hip System.

90. The Defendants' Hip System, which was researched, developed, designed, tested, manufactured, inspected, labeled, distributed, marketed, promoted, sold and otherwise released into the stream of commerce by Defendants, was defective due to inadequate post-marketing warnings and/or instruction because, after Defendants knew or should have known that there was reasonable evidence of an association between the Defendants' Hip System components and the development of corrosion, metal fatigue, failure, micromotion and/or release of significant amounts of metal debris and/or dislocations, causing serious injury and pain, Defendants failed to provide adequate warnings to health care professionals and the consuming public, including Plaintiff, and continued to aggressively promote the Defendants' Hip System.

91. The Defendants' Hip System, which was researched, developed, designed, tested, manufactured, inspected, labeled, distributed, marketed, promoted, sold

and otherwise released into the stream of commerce by Defendants, was defective due to inadequate post-marketing warnings and/or instruction regarding the increased risk of failure of the Defendants' Hip System resulting in revision surgery while knowing that a safer alternative design including, the use of a ceramic femoral head and monoblock stem components existed.

92. Defendants failed to perform or otherwise facilitate adequate testing; failed to reveal and/or concealed testing and research data; and selectively and misleadingly revealed and/or analyzed testing and research data.

93. Plaintiff and her physician, used the Defendants' Hip System for its intended purpose, i.e., hip replacement.

94. Plaintiff could not have discovered any defect in the Defendants' Hip System through the exercise of due care.

95. Defendants, as designers, manufacturers, distributors, promoters, marketers and/ or sellers of medical devices are held to the level of knowledge of experts in their field.

96. Neither Plaintiff nor her implanting physician had substantially the same knowledge about the Defendants' Hip System as Defendants.

97. Defendants reasonably should have known the device was unsuited for active individuals such as Plaintiff.

98. The warnings and instructions provided with the Defendants' Hip System did not adequately educate and train medical providers as to the risk of side effects, or the cost-benefit analysis necessary for justified use of this product versus safer alternative designs.

99. Defendants had a continuing duty to warn the medical community and public, including Plaintiff and Plaintiff's healthcare providers, of the potential risks and increased failure rates or propensity for failure associated with the Defendants' Hip System.

100. As a direct and proximate result of Defendants' failure to adequately

communicate a warning and/or failure to provide an adequate warning and other wrongful conduct as set forth herein, Plaintiff has sustained and will continue to sustain severe physical injuries, severe emotional distress, mental anguish, economic losses and other damages, as set forth herein.

101. As a direct result of Defendants' failure to warn and/or inadequate warning and their other tortious conduct, Plaintiff has suffered serious physical injury, harm, damages and economic loss and will continue to suffer such harm, damages and economic loss in the future.

102. As a direct and proximate result of Defendants' failure to warn and/or inadequate warning and their other tortuous conduct, as set forth herein, Plaintiff has suffered and will continue to suffer injuries, damages and losses, and is entitled to compensatory damages in an amount to be determined by the trier of fact.

THIRD CAUSE OF ACTION

Strict Products Liability – Manufacturing Defect

103. Plaintiff incorporates by reference paragraphs 1 through 102 of this Complaint, as if fully set forth herein and further allege as follows:

104. Defendants designed, developed, manufactured, tested, packaged, advertised, promoted, marketed, distributed, labeled and/or sold Defendants' Hip System, in a condition which rendered it unreasonably dangerous due to its propensity to result in early failure of the device. The subject product was unreasonably dangerous in construction or composition.

105. The Defendants' Hip System manufactured and/or supplied by Defendants was defective in manufacture, construction or composition in that, when it left the hands of Defendants, it deviated in a material way from Defendants' manufacturing performance standards and/or it differed from otherwise identical products manufactured to the same design formula. Defendants knew or should have known that their Hip System could fail early in patients therefore giving rise to pain and suffering,

debilitation and the need for revision surgeries to replace the device with the attendant risks of complications and death from such further surgeries, but Defendants continued to market the Defendants' Hip System as a safe and effective hip replacement system.

106. As a direct and proximate result of the use of the subject product as manufactured, designed, sold, supplied and introduced into the stream of commerce by Defendant, Plaintiff suffered harm, damages and economic loss as previously described and will continue to suffer such harm, damages and economic loss in the future.

FOURTH CAUSE OF ACTION

Negligence

107. Plaintiff incorporates by reference paragraphs 1 through 106 of this Complaint, as if fully set forth herein and further allege as follows:

108. While the focus of Plaintiff's strict liability claims (Counts I-III) is on the condition of the product, the focus of Plaintiff's negligence claim is instead on Defendants' conduct.

109. Defendants had a duty to exercise reasonable care in the design, formulation, manufacture, testing, quality assurance, quality control, labeling, and/or warning of the Defendants' Hip System, including a duty to assure that their products did not pose a significantly increased risk of bodily harm and adverse events.

110. Defendants failed to exercise ordinary care in the design, formulation, manufacture, testing, quality assurance, quality control, labeling, and warning of the Defendants' Hip System devices in that they knew or should have known that these products caused significant bodily harm and were not safe for use by consumers.

111. Defendants failed to exercise ordinary care in the sale marketing, promotions and distribution of the Defendants' Hip System devices in that they knew or should have known that these products caused significant bodily harm and were not safe for use by consumers.

112. The Defendants failed to exercise ordinary care in testing their Hip System prior to marketing, sale and distribution of it.

113. At all relevant times, Defendants had a duty to exercise reasonable care in the design, formulation, testing, manufacture, marketing, sale, and distribution of the Defendants' Hip System, including a duty to ensure that the Hip System did not pose a significantly increased risk of bodily injury to its users.

114. Defendants had a duty to exercise reasonable care in the advertising and sale of the Defendants' Hip System, including a duty to warn Plaintiff and other consumers, of the dangers associated with the Defendants' Hip System that were known or should have been known to Defendants at the time of the sale to the Plaintiff.

115. Defendants failed to exercise reasonable care in the design, testing, manufacture, marketing, sale and distribution of the Defendants' Hip System because Defendants knew or should have known that the Defendants' Hip System had a propensity to cause serious injury, including adverse local tissue reaction, pseudotumor formation, metal debris, corrosion, metal ions, excessive wear, tissue necrosis, pain, swelling, metal ion release, loosening of the implants, bone loss, decreased range of motion, diminished mobility, and revision surgeries.

116. Defendants failed to exercise ordinary care in the labeling of the Hip System and failed to issue adequate pre-marketing or post-marketing warnings to doctors and the general public, including Plaintiff, regarding the risk of serious injury, including adverse local tissue reaction, pseudotumor formation, metal debris, corrosion, metal ions, excessive wear, tissue necrosis, pain, swelling, metal ion release, loosening of the implants, bone loss, decreased range of motion, diminished mobility, and revision surgeries.

117. Defendants knew or should have known that Plaintiff could foreseeably suffer injury as a result of Defendants' failure to exercise ordinary care as described above.

118. Defendants breached their duty of reasonable care to Plaintiff by failing to exercise due care under the circumstances as follows:

a. Failing to use due care in the development, design, formulation, manufacturing, labeling, testing, assembly,

marketing, advertising, promotion, inspection, sale and/or distribution of the Defendants' Hip System, and/or to utilize and/or implement reasonably safe designs for them;

b. At all times relevant hereto, Defendants knew or should have known that the design of the Defendants' Hip System was generating the potential for metal on metal problems, vulnerabilities, and injuries;

c. Defendants failed to perform sufficient clinical trials and other pre-marketing evaluations to determine risk and efficacy of the Defendants' Hip System;

d. Such testing would have revealed the increased risk of failure and tendency to cause significant corrosion, metal wear debris, metal byproduct release, resulting in necrosis, pain, swelling, adverse local tissue reaction, trunnionosis, and/or metallosis;

e. A reasonable manufacturer under the same or similar circumstances would have conducted additional testing and evaluation of the Defendants' Hip System before placing it into the stream of commerce;

f. A reasonable manufacturer under the same or similar circumstances would have conducted adequate testing of all junctions coupled with the cobalt-chromium femoral head and evaluation of the Defendants' Hip System before placing it into the stream of commerce;

g. A reasonable manufacturer under the same or similar circumstances would have required that significant information be provided to physicians regarding the risks associated with foreseeable metal on metal problems stemming from the design;

h. At all times relevant hereto, Defendants knew or should have known of the serious complications and high failure rate associated with the Defendants' Hip System;

i. Failing to provide adequate and proper warnings to the public and to Plaintiff of the dangerous propensities of the Defendants' Hip System when used in a reasonably foreseeable manner;

j. Failed to conduct adequate post marketing surveillance;

k. Failing to design, formulate, manufacture and incorporate or to reformulate the Defendants' Hip System with reasonable safeguards and protections against the type of injury and damage suffered by Plaintiff when used in a reasonably foreseeable manner;

l. Failing to adequately prevent, identify, mitigate, and fix defective designs and hazards associated with the Hip System in accordance with good design practices;

m. Failing to notify and warn the public including Plaintiff, of reported incidents involving injury, etc., and the negative health effects attendant to the use of the Hip System, thus misrepresenting the safety of the product;

n. Failing to make timely and adequate corrections to the manufacture, design and formulation of the Hip System so as to prevent and/or minimize the problems suffered by the Defendants' Hip System use;

o. Despite its knowledge of these risks, Defendants continued to promote and market the device; and,

p. Being otherwise careless, reckless and negligent.

119. Despite knowing or having reason to know of the risks, Defendants did not

(1) perform additional testing, (2) investigate the risks, (3) suspend sales or distribution, (4) warn physicians or patients of the propensity for the Defendants' Hip System to cause or create significant corrosion, metal wear debris, metal byproduct release, resulting in necrosis, pain, swelling, dislocation, osteolysis, pseudotumor formation, adverse local tissue reaction, trunnionosis, metallosis, and/or need for early surgical revisions.

120. As a direct and proximate result of Defendants' acts and omissions, including their failure to exercise ordinary care in the design, formulation, testing, manufacture, sale, labeling, warnings and distribution of the Defendants' Hip System, Plaintiff was implanted with the Defendants' Hip System and suffered severe and debilitating injuries, economic loss, and other damages, including but not limited to, cost of medical care, rehabilitation, lost income, permanent instability and loss of balance, immobility, and pain and suffering, for which she is entitled to compensatory and equitable damages and declaratory relief in an amount to be proven at trial.

FIFTH CAUSE OF ACTION

Negligent Misrepresentation

121. Plaintiff incorporates by reference paragraphs 1 through 120 of this Complaint, as if fully set forth herein and further allege as follows:

122. Prior to the Plaintiff receiving the Defendants' Hip System, Defendants misrepresented that the Defendants' Hip System was a safe and effective total hip replacement system.

123. In the exercise of reasonable care, Defendants should have known that the Defendants' Hip System devices failed to comply with federal requirements for safe design and manufacture and/or was in other ways out of specification, yet they negligently misrepresented to Plaintiff and/or his physician that their device was safe and met all applicable design and manufacturing requirements.

124. Defendants failed to disclose material facts regarding the safety and efficacy of the Defendants' Hip System utilizing a CoCr femoral head, including information regarding increased risk of failure, harmful side-effects, increased risk of

revision surgeries and lack of adequate testing.

125. Defendants had a duty to provide Plaintiff, physicians and other consumers with true and accurate information and warnings of any known risks and harmful side effects of the medical devices they marketed distributed and sold.

126. Defendants knew or should have known, based on prior experience, adverse event reports, studies and knowledge of the efficacy and safety failures associated with the Defendants' Hip System, that their representations regarding the Hip System were false, and that they had a duty to disclose the dangers associated with the devices.

127. Plaintiff and her physicians reasonably relied to Plaintiff's detriment upon Defendants' misrepresentations and material omissions in their marketing, advertisements, and promotions concerning the quality and safety of the Defendants' Hip System.

128. Plaintiff and his physicians reasonably relied upon Defendants' representations that the Defendants' Hip System was of high quality and safe for implantation into her body.

129. Defendants made the representations and failed to disclose the material facts with the intent to induce consumers, including the Plaintiff, and the medical community to act in reliance by purchasing the Defendants' Hip System with a CoCr femoral head.

130. Defendants' representations and nondisclosures regarding the safety and efficacy of the Defendants' Hip System was the direct and proximate cause of Plaintiff's injuries.

131. Defendants' conduct, as described above, was reckless. Defendants risked the lives of consumers and users of their products, including Plaintiff, with knowledge of the safety and efficacy problems and suppressed this knowledge from the general public. Defendants made conscious decisions not to redesign, re-label, warn or inform the unsuspecting consuming public. Defendants' reckless conduct warrants an award of punitive damages.

132. Plaintiff and/or her physician justifiably relied to their detriment upon

Defendants' misrepresentations and omissions in their marketing, advertisements, promotions and labeling concerning these products.

133. Plaintiff and/or her physician justifiably relied upon Defendants' representations that the Defendants' Hip System devices were safe for use in persons such as Plaintiff.

134. As a direct and proximate result of Defendants' negligent misrepresentations and/or omissions regarding the Defendants' Hip System devices, Plaintiff used the devices and has suffered serious physical injury, harm, damages and economic loss and will continue to suffer such harm, damages and economic loss in the future.

135. As a direct and proximate result of Defendants' negligent misrepresentations, Plaintiff has suffered and will continue to suffer injuries, damages and losses, and is entitled to compensatory damages in an amount to be determined by the trier of fact.

SIXTH CAUSE OF ACTION

Breach of Express Warranty

136. Plaintiff incorporates by reference paragraphs 1 through 135 of this Complaint, as if fully set forth herein and further allege as follows:

137. Defendants advertised, labeled, marketed and promoted the Hip System, representing the quality to health care professionals, the FDA, Plaintiff, and the public in such a way as to induce its purchase or use, thereby making an express warranty that the Defendants' Hip System would conform to the representations. More specifically, Defendants represented that the Hip System was safe and effective, that it was safe and effective for use by individuals such as Plaintiff, and/or that it was safe and effective to treat Plaintiff's condition.

138. The representations, as set forth above, contained or constituted affirmations of fact or promises made by the seller to the buyer which related to the goods and became part of the basis of the bargain creating an express warranty that the goods shall conform to the affirmations of fact or promises.

139. The Defendants' Hip System did not conform to the representations

made by Defendants in that the Defendants' Hip System was not safe and effective, was not safe and effective for use by individuals such as Plaintiff, and/or was not safe and effective to treat in individuals, such as Plaintiff.

140. At all relevant times, Plaintiff used the Defendants' Hip System for the purpose and in the manner intended by Defendants.

141. Plaintiff and Plaintiff's physicians, by the use of reasonable care, could not have discovered the breached warranty and realized its danger.

142. The breach of the warranty was a substantial factor in bringing about Plaintiff's injuries.

142. Within a reasonable time after Plaintiff knew or should have known of the failure of his Defendants' Hip System components, Plaintiff gave notice to Defendants of such failure.

143. Defendants breached the express warranty it provided with the devices.

144. As a direct and proximate result of Defendants' acts and omissions, including their failure to exercise ordinary care in the design, formulation, testing, manufacture, sale, and distribution of the Defendants' Hip System, Plaintiff was implanted with the Defendants' Hip System and suffered severe and debilitating injuries, economic loss, and other damages, including but not limited to, cost of medical care, rehabilitation, lost income, permanent instability and loss of balance, immobility, and pain and suffering, for which he is entitled to compensatory and equitable damages and declaratory relief in an amount to be proven at trial.

SEVENTH CAUSE OF ACTION

Breach of Implied Warranty

145. Plaintiff incorporates by reference paragraphs 1 through 144 of this Complaint, as if fully set forth herein and further allege as follows:

146. The Defendants' Hip System was not reasonably fit for the ordinary purposes for which such goods are used and did not meet the expectations for the performance of the product when used in the customary, usual and reasonably foreseeable manner. Nor was the Defendants' Hip System minimally safe for its expected

purpose.

147. At all relevant times, Plaintiff used the Defendants' Hip System for the purpose and in the manner intended by Defendants.

148. Plaintiff and Plaintiff's physicians, by the use of reasonable care could not have discovered the breached warranty and realized its danger.

149. The breach of the warranty was a substantial factor in bringing about Plaintiff's injuries.

150. Defendants impliedly warranted that the Defendants' Hip System and its component parts were merchantable and fit for the ordinary and intended purposes for which hip systems are used.

151. Plaintiff was a foreseeable user of the Defendants' Hip System.

152. Plaintiff's surgeon, as purchasing agent, purchased the Hip System for Plaintiff from Defendants.

153. At all times relevant to this Complaint, Plaintiff was and is in privity with Zimmer.

154. Plaintiff used the products for their ordinary and intended purpose.

155. The Defendants' Hip System failed while being used for its ordinary and intended purpose.

156. As a direct and proximate result of Zimmer's breach of implied warranty of merchantability, Plaintiff suffered injuries as described specifically above.

PRAYER FOR RELIEF

WHEREFORE, Plaintiff prays for judgment and an award of damages against Defendants, as follows:

(a) for special damages, to include past and future medical and incidental expenses, according to proof;

(b) for past and future loss of earnings and/or earning capacity, according to proof;

(c) for past and future general damages, to include pain and suffering, emotional distress and mental anguish, according to proof;

(d) for pre-judgment and post-judgment interest;

(e) for the costs of this action;

(f) granting any and all such other and further legal and equitable relief as the Court deems necessary, just and proper; and,

(g) awarding treble and/or punitive damages to Plaintiff.

DEMAND FOR TRIAL BY JURY

Plaintiff hereby demands a trial by jury to the full extent permitted by law.

Date: April 20, 2022

JOSEPH FARZAM LAW FIRM

Michael P. Green
Attorneys for Plaintiff Latonia Crawford

PROOF OF SERVICE

1013A (3) CCP

STATE OF CALIFORNIA, COUNTY OF LOS ANGELES

I am employed in the County of Los Angeles, State of California. I am over the age of 18 and not a party to the within action; my business address is 11766 Wilshire Blvd., Suite 280, Los Angeles, CA 90025.

On **May 5, 2022** I served the foregoing document(s) described **NOTICE OF MOTION AND MOTION TO FILE AMENDED COMPLAINT,** on the interested parties in this action by placing a true copy thereof enclosed in a sealed envelope addressed as follows:

SEE ATTACHED SERVICE LIST

( ) BY MAIL: I am "readily familiar" with the firm's practice of collection and processing correspondence for mailing. Under that practice, it would be deposited with the U.S. Postal Service on the same day with postage thereon fully prepaid at Los Angeles, California, in the ordinary course of business. I am aware that on motion of the party served, service is presumed invalid if postal cancellation or postage meter date is more than one day after date of deposit for mailing in affidavit.

( ) BY PERSONAL SERVICE: I delivered such envelope by hand to the offices of the addressee(s).

(X) BY ELECTRONIC SERVICE: pursuant to Code of Civil Procedure § 1010.6(a)(2)(A)(i), 1010.6(a)(2)(A)(ii), and/or necessity resulting from the Safer at Home order/regulation issued by the City and County of Los Angeles effective March 20, 2020: from my email address wendy@farzamlaw.com to the e-mail address(es) listed BELOW:

amy.heiserman@quarles.com

Executed on **May 5, 2022** in Los Angeles, California.

I declare under penalty of perjury under the laws of the State of California that the above is true and correct.

Wendy Fabian, J.D.

SERVICE LIST

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